

TubeClear™ Operator's Manual

In-patient Nasogastric Tube Clearing System

- + Read this Manual before using TubeClear™. Failure to follow the cautions and instructions in this Manual constitutes abnormal use and can result in injury.
- + For use with TubeClear™ Control Box Model 101 and Clearing Stem Models NG-1043 and NG-1036.



Innovative motion + Positive outcomes



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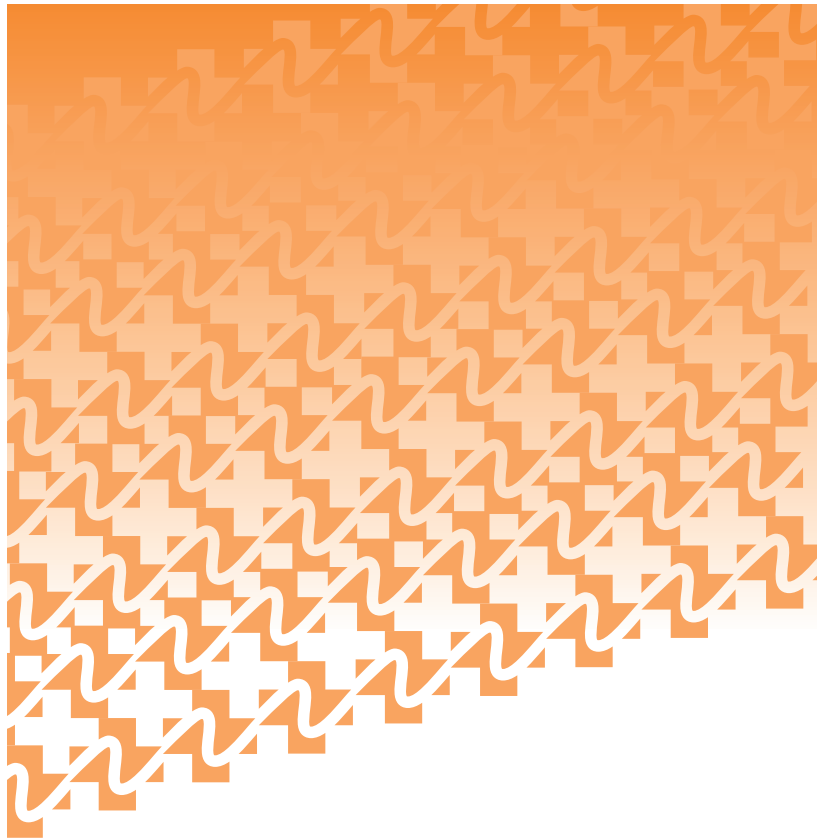
PATENT PENDING



Innovative motion + Positive outcomes

Keep this Manual in a safe location for future reference.

 
DOC# ECO1219
PATENT PENDING



Operator Assistance Information

If you have questions regarding the use of TubeClear™ please contact:

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8:00 am - 5:00 pm U.S.A. Eastern Standard Time

Training Materials

Training materials are accessible on our website at TubeClear.com.

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1.0 Intended Use

TubeClear™ is intended to clear occlusions / clogs in nasogastric feeding and decompression tubes.

TubeClear™ consists of a reusable Control Box Model 101 and single use Clearing Stem Models NG-1036 and NG-1043.

1.1) Indications for Use

TubeClear™ is indicated for use only and solely in clearing occlusions / clogs in nasogastric (NG) tubes (i.e., tubes that are placed through the nose and reside in the stomach) of adult patients. Clearing Stem Model NG-1036 is intended for use in nasogastric tubes that are labeled 10 - 14 French and have a length of 36 - 42 in (91-108 cm). Clearing Stem Model NG-1043 is intended for use in nasogastric tubes that are labeled 10 - 18 French and have a length of 43 - 50 in (109 -127 cm).

1.2) Contraindications

TubeClear™ is **NOT** intended for use in jejunostomy tubes (J tubes), percutaneous endoscopic gastrostomy tubes (PEG tubes), gastrostomy-jejunostomy tubes (GJ tubes), or nasojejunal tubes (NJ tubes).

Do NOT use TubeClear™ if:

- + You are **NOT** certain that the Patient has a nasogastric (NG) tube.
- + You do **NOT** know for certain the size and length of the Patient's nasogastric tube.
- + The TubeClear™ Clearing Stem model is **NOT** available for the size and length of the Patient's nasogastric tube.
- + The nasogastric tube has been removed from the Patient.
- + The Patient is less than 18 years old.
- + The nasogastric tube requires placement or repositioning.

2.0 Cautions

Read the entire manual before using TubeClear™. Disregarding the cautions and instructions presented in this manual constitutes ABNORMAL USE.

Over insertion of the TubeClear™ Clearing Stem may cause harm to the Patient's stomach lining. **Take care to make certain that the correct Clearing Stem model has been selected for the size and length of the Patient's nasogastric tube.** Refer to **Section 5.0** Operating Instructions, for guidance on verifying correct selection of the Clearing Stem.



If the nasogastric tube is removed, do **NOT** clear and re-insert the same nasogastric tube. TubeClear™ is intended to be used with the nasogastric tube residing **IN THE PATIENT**. If the nasogastric tube has been removed from the Patient, follow your Institution's Protocol for insertion of a new nasogastric tube.



TubeClear™ may cause some discomfort to the nasal passage during use.



TubeClear™ contains magnets. Magnets are inside the Control Box and at the end of the Clearing Stem that attaches to the Control Box. Do **NOT** place the Control Box and the Magnet at the end of the Clearing Stem within 6 in (15 cm) of pacemakers, defibrillators and other electronic devices (*including, but not limited to, credit cards, video tapes, televisions, computer monitors and other CRT displays*) because the magnets may interfere with the operation of those devices.



Ensure that the Control Box is securely mounted to an IV pole or level table to reduce the risk of the Control Box falling.



TubeClear™ is non-sterile. It is intended for use with nasogastric (NG) tubes and does **NOT** require sterile conditions for its intended purpose. Do **NOT** use TubeClear™ in any manner that would require sterile conditions.

 Federal law (U.S.) restricts TubeClear™ to sale by or on the order of a physician.

	Attention, read instructions before use.
	Do NOT operate in the presence of flammable anesthetics. (Flammable anesthetics are gases or vapors, including, but not limited to, fluroxene, ethyl chloride, ethyl ether and ethylene, which may form flammable or explosive mixtures with air, oxygen or reducing gases such as nitrous oxide.)
	Do NOT dispose the Clearing Stem or any de-clogged contents from the nasogastric tube with ordinary waste. Dispose as regulated medical waste in accordance with applicable government regulations and your Institution's Protocol.
	The TubeClear™ Clearing Stems are SINGLE USE .

3.0 Device Description

Operator Profile

TubeClear™ is intended for use by licensed practical nurses (LPNs), registered nurses (RNs), or physicians.

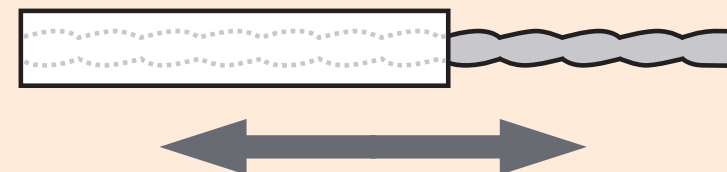
TubeClear™ is a device for clearing clogs in nasogastric (NG) tubes while the tube **REMAINS** in the Patient. TubeClear™ consists of a reusable Control Box and a single use Clearing Stem. The Clearing Stem magnetically attaches to the Control Box.

Clogs are occlusions, blockages, or obstructions of feeding formula, medications, supplements, or aspirated contents in the nasogastric tube.

The Clearing Stem consists of an 80 in (203 cm) long, flexible Wire encased in a flexible Sheath. The outer diameter of the Wire is approximately 1/32 in (0.07 cm) and the outer diameter of the Sheath is approximately 1/16 in (0.17 cm). The tip of the Wire is rounded and smooth. The tip extends approximately 1 in (2.54 cm) beyond the Sheath.

The Control Box contains a Motor that activates the Clearing Stem Wire. The Motor causes the Wire to move quickly forward and backward inside the Sheath. The Wire moves approximately 1/8 -

FIGURE 1: Wire in Sheath. The Wire moves forward and backward inside the Sheath.



1/2 in (0.4 - 1.1 cm) as illustrated in **Figure 1**. This backward and forward movement of the Wire allows it to break up and clear clogs within nasogastric tubes while the tube remains in the Patient. Each Clearing Stem has a Collar permanently attached. The Collar limits insertion depth of the Clearing Stem so that the Tip of the Wire does not extend beyond the end of the nasogastric tube's distal ports into the Patient's stomach.

Because nasogastric tubes come in different sizes and lengths, two (2) models of TubeClear™ Clearing Stems are available. The TubeClear™ Clearing Stem models currently available are listed in **Table 1**.

TABLE 1: TubeClear™ Clearing Stem Models

Nasogastric (NG) Tube Measurements				Proper Product Selection	
NG Tube Type	French Size (Fr)	Tube Length (in)	Tube Length (cm)	Model #	Stem Color
Feeding Tube	10 - 14	36 - 42	91 - 108	NG-1036	Clear
Feeding Tube	10 - 14	43 - 50	109 - 127	NG-1043	Green
Sump Tube	10 - 18	43 - 50	109 - 127	NG-1043	Green
Levin Tube	10 - 14	43 - 50	109 - 127	NG-1043	Green

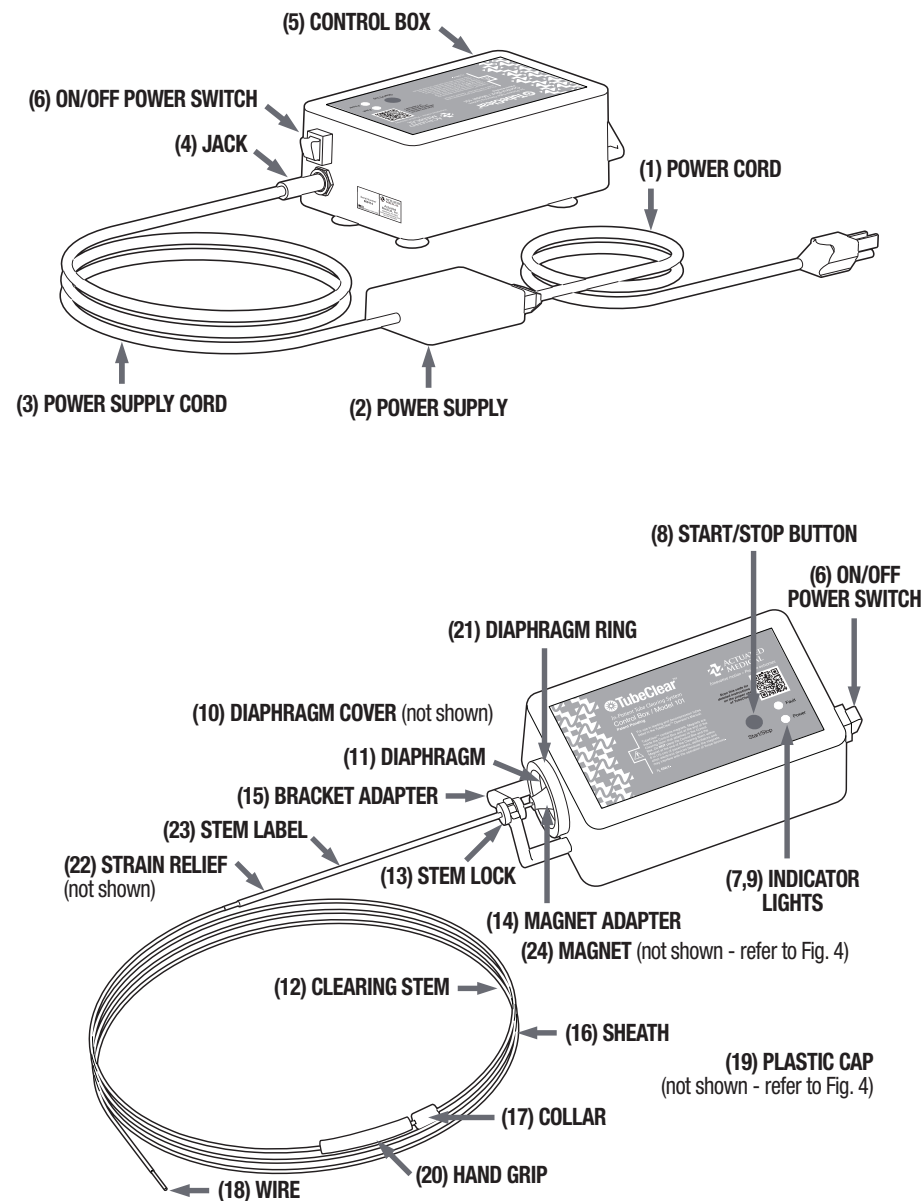
TubeClear™ is externally powered. A Power Cord and a Power Supply are included with TubeClear™. The Power Cord plugs into a standard wall outlet (100 - 240 V @ 50/60 Hz). The Power Supply reduces the voltage to 25 VDC.

TubeClear™ components are listed and numbered in **Table 2** (see page 5) and are shown with corresponding item numbers in **Figure 2** (see page 6).

TABLE 2: TubeClear™ Component List

Item No.	Name	Description
1	Power Cord	Plugs into a standard three-prong outlet and into the Power Supply.
2	Power Supply	Reduces voltage to TubeClear™.
3	Power Supply Cord	Plugs into the Jack on the Control Box.
4	Jack	Connector for Power Supply.
5	Control Box	Contains the Motor and drive electronics.
6	On/Off Power Switch	Allows power to the Control Box.
7	Green Indicator Light	Indicates power is available and is ready to start.
8	Start/Stop Button	Starts and stops the Motor inside the Control Box.
9	Yellow Indicator Light	Indicates an electrical fault. TubeClear™ will not operate when the yellow light is on.
10	Diaphragm Cover	Covers and protects the Diaphragm during storage.
11	Diaphragm	Clearing Stem attachment point.
12	Clearing Stem	Inserts into nasogastric tube to clear clogs, while the tube remains inside the patient.
13	Stem Lock	Fits within the Bracket Adapter, secures the Clearing Stem.
14	Magnet Adapter	Secures the Magnet on the end of the Clearing Stem.
15	Bracket Adapter	Holds and positions the Clearing Stem during use.
16	Sheath	The flexible tubing that surrounds the Wire.
17	Collar	Feature limits insertion depth of the Clearing Stem.
18	Wire	Feature that interacts with the clog material.
19	Plastic Cap	Covers and protects Magnet Adapter during storage.
20	Hand Grip	Feature for locating hand during insertion.
21	Diaphragm Ring	Feature to secure Diaphragm to Control Box.
22	Strain Relief	Feature to minimize Clearing Stem bend at Control Box.
23	Stem Label	Describes Model and intended nasogastric tube.
24	Magnet	Feature to attach Clearing Stem to Control Box.

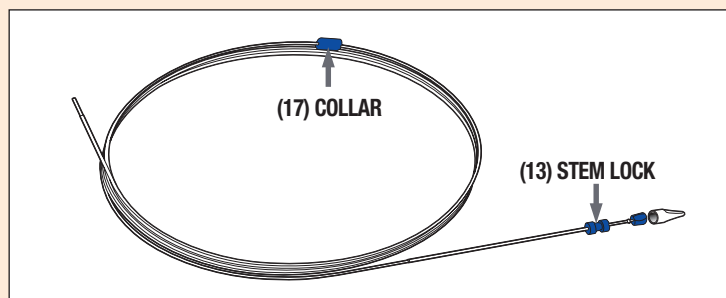
FIGURE 2: TubeClear™ Component Locations



4.0 Set-up Instructions

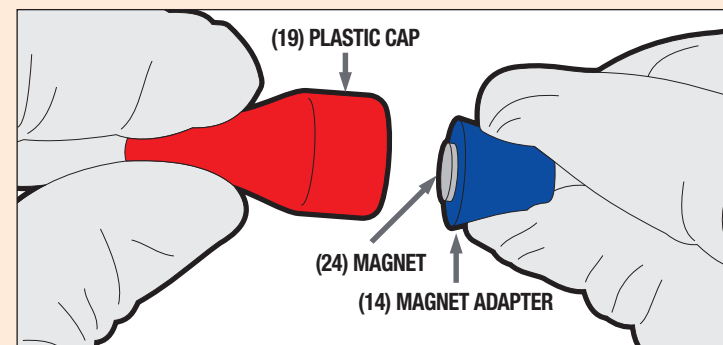
- 4.1) Verify that you have the correct TubeClear™ Clearing Stem model for the size of nasogastric tube. Refer to **Table 1** in **Section 5.0** for model selection.
- 4.2) Place the Control Box on a level table to reduce the risk of the Control Box falling.
- 4.3) **NOTE:** It may be helpful to reference **Figure 2** when reading through the Set-up Instructions.
- 4.4) Verify that the Power Cord (1) is securely plugged into the Power Supply (2).
- 4.5) Plug the Power Cord (1) into a standard 100 - 240 V @ 50/60 Hz three-prong outlet.
- 4.6) Plug the Power Supply Cord (3) into the Jack (4) on the Control Box (5).
- 4.7) Verify that the Control Box (5) is operational by turning the On/Off Power Switch (6) to the **ON** position.
- 4.8) The Green Indicator Light (7) will illuminate when the Control Box (5) is operational. **NOTE:** The Control Box Motor will not start at this time. The Start/Stop Button (8) needs to be pushed down before the Control Box Motor will operate.

FIGURE 3: The Collar and Stem Lock Locations.



- 4.9) If the Yellow Indicator Light (9) illuminates, do **NOT** use the Control Box (5). Turn the power off and then back on (cycle the power). If the Yellow Indicator Light remains on, see **Section 9.0** Return Policy.
- 4.10) Remove the Diaphragm Cover (10) from the Diaphragm (11).
- 4.11) Remove the Clearing Stem (12) from its Packaging. Do **NOT** discard the Packaging.
- 4.12) Verify that both the Collar (17) and the Stem Lock (13) are attached, as illustrated in **Figure 3**. If they are not securely attached, obtain a new Clearing Stem (12). Do **NOT** use a Clearing Stem without a Collar because the Collar limits insertion depth.
- 4.13) Pull the Plastic Cap (19) from the Magnet Adapter (14) at the end of the Clearing Stem (12) as illustrated in **Figure 4**. Place the Plastic Cap inside the Packaging. Immediately place the Magnet Adapter of the Clearing Stem to the center of the Diaphragm (11) of the Control Box (5) as shown in **Figure 5** (see page 9). Do **NOT** attach the Magnet Adapter to other metal surfaces.
- 4.14) The Magnet Adapter (14) will adhere magnetically to the center of the Diaphragm (11) as shown in **Figure 5**. Pull gently on the Magnet Adapter to confirm that it is securely attached. There

FIGURE 4: Removal of the Plastic Cap from the Magnet Adapter.



will be resistance if the Magnet Adapter is properly attached. If the Magnet Adapter is not attached securely, reposition the Magnet Adapter onto the Diaphragm center.

FIGURE 5: Attachment of the Magnet Adapter to the Diaphragm.

Position the Magnet Adapter in the center of the Diaphragm. Pull slightly to confirm the Magnet Adapter is attached securely.

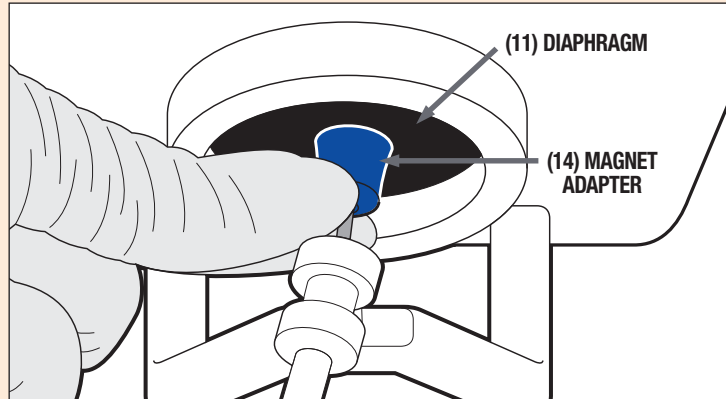
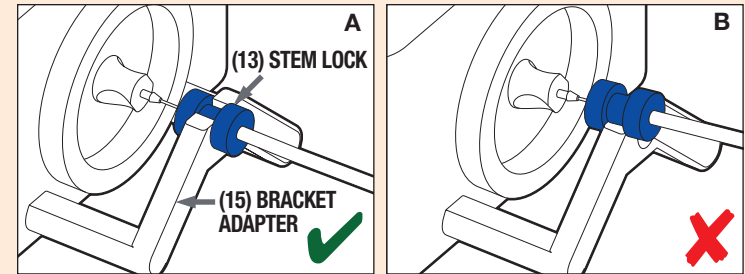


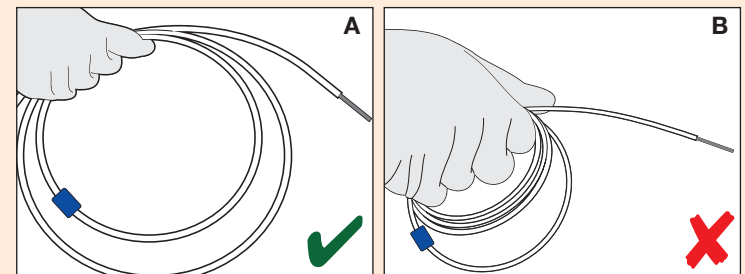
FIGURE 6: (A) Correct Placement of the Stem Lock in the Bracket Adapter. Place the Stem Lock securely in the Bracket Adapter for optimum performance. **(B) Incorrect Placement of the Stem Lock in the Bracket Adapter.** Do **NOT** operate the Control Box if the Stem Lock is not seated correctly on the Bracket Adapter.



- 4.15) Firmly place the Stem Lock (13) into the Bracket Adapter (15) and verify the connection is secure. **Figure 6A** shows the correct Stem Lock placement. Proper placement of the Stem Lock is necessary for effective operation.
- 4.16) Do **NOT** operate TubeClear™ if Stem Lock (13) is not securely placed in Bracket Adapter (15). Incorrect placement of Stem Lock as shown in **Figure 6B** will cause TubeClear™ to operate inefficiently.
- 4.17) You may loosely coil the Clearing Stem (12) around your hand to help control the Clearing Stem length while inserting it into the nasogastric tube (see **Figure 7A**).

- 4.18) Do **NOT** tightly coil the Clearing Stem (12) around your hand as shown in **Figure 7B** before or during use because this will slow the Wire (18) motion inside the Sheath (16) and decrease efficacy. Refer to **Figure 7** for guidance on how to hold the Clearing Stem.

FIGURE 7: (A) Correct Handling of the Clearing Stem. Loosely wrap the Clearing Stem around your hand as the Clearing Stem is inserted into the nasogastric tube. **(B) Incorrect Handling of the Clearing Stem.** Do **NOT** tightly coil the Clearing Stem around your hand before or during use because this will slow the Wire motion inside the Sheath and decrease efficacy.



5.0 Operating Instructions

- 5.1) Read the Operating Instructions and review **Flow Diagrams A and B** before operating TubeClear™.
- 5.2) TubeClear™ is to be used while the nasogastric tube is **in the Patient**. Do **NOT** remove the nasogastric tube to use TubeClear™.
- 5.3) It is recommended that Operators wear eye protection and gloves when operating TubeClear™.
- 5.4) It is recommended that a disposable pad be placed over the Patient's chest and stomach area during use of TubeClear™.
- 5.5) If the Control Box (5) appears to be damaged do **NOT** use TubeClear™. If damaged, replace the Control Box with a new Control Box. See **Section 9.0** Return Policy.
- 5.6) If you do **NOT** know that the tube is nasogastric (*distal end resides in the stomach*), do **NOT** use TubeClear™.
- 5.7) Verify the length of the Patient's nasogastric tube.
- 5.8) If you do **NOT** know the **length** of the Patient's nasogastric tube, do **NOT** use TubeClear™.
- 5.9) If a TubeClear™ Clearing Stem model is not available for the size and length of the nasogastric tube to be cleared, do **NOT** use TubeClear™.
- 5.10) Refer to **Table 1** for a listing and description of TubeClear™ models.

TABLE 1: TubeClear™ Clearing Stem Models

Nasogastric (NG) Tube Measurements				Proper Product Selection	
NG Tube Type	French Size (Fr)	Tube Length (in)	Tube Length (cm)	Model #	Stem Color
Feeding Tube	10 - 14	36 - 42	91 - 108	NG-1036	Clear
Feeding Tube	10 - 14	43 - 50	109 - 127	NG-1043	Green
Sump Tube	10 - 18	43 - 50	109 - 127	NG-1043	Green
Levin Tube	10 - 14	43 - 50	109 - 127	NG-1043	Green

Examples: If the Patient has a nasogastric tube, 10 Fr, 36 in (91 cm) long, select Model Number NG-1036 (Clear Color).

If the Patient has a nasogastric tube, 12 Fr, 45 in (114 cm) long, select Model Number NG-1043 (Green Color).

If the Patient has a Sump Tube 18 Fr, 48 in (122 cm) long, select Model Number NG-1043 (Green Color).

- 5.11) Verify that the model selected is correct for the Tube Type, French Size and Length to be cleared.

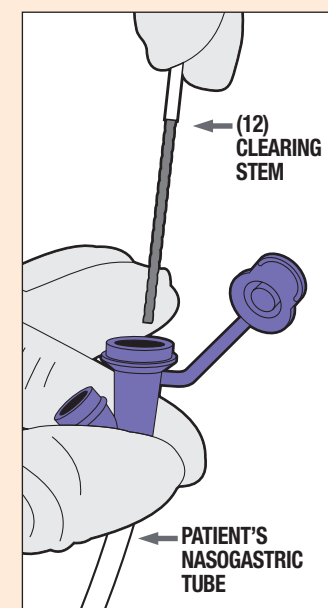


Failure to use the correct Clearing Stem (12) could result in over insertion of the Clearing Stem.

The label on the Clearing Stem Packaging will identify the Model and indicate the nasogastric tube size(s) and length(s) that the Clearing Stem will unclog.

- 5.12) Set-up TubeClear™ and attach the Clearing Stem (12) as directed in **Section 4.0** Set-up Instructions.
- 5.13) Do **NOT** press down the Start/Stop Button (8) until Step 5.17.
- 5.14) Hold the Patient's nasogastric tube in one hand and the Clearing Stem (12) in your other hand, illustrated in **Figure 8**.
- 5.15) Insert the Clearing Stem (12) into the nasogastric tube only a few inches (centimeters) at this time.

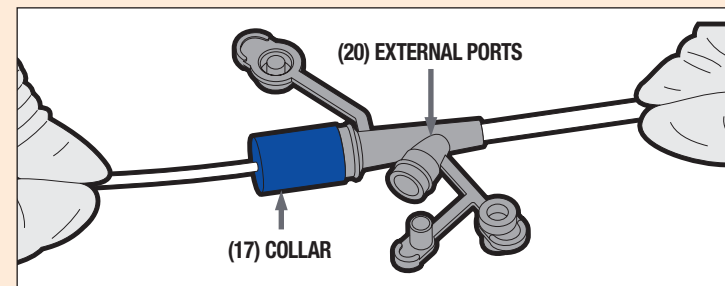
FIGURE 8: Insertion of the TubeClear™ Clearing Stem into Nasogastric Tube. Hold the Patient's nasogastric tube in one hand and the Clearing Stem in your other hand.



- 5.16) Switch the On/Off Power Switch (6) to the **ON** position and verify that the Green Indicator Light (7) turns on.
- 5.17) Hold both the nasogastric tube and the Clearing Stem (12) with one hand and press down the Start/Stop Button (8) with your other hand until Control Box (5) beeps (approximately 2 seconds).
- 5.18) Hold the Patient's nasogastric tube in one hand and slowly advance the Clearing Stem (12) with your other hand into the nasogastric tube.
- 5.19) Continue advancing the Clearing Stem (12) until it no longer moves forward.
- 5.20) If the Clearing Stem (12) stops progressing forward before the Collar (17) reaches the nasogastric tube's external port, apply slight, gentle pressure to the Clearing Stem. Do **NOT** force the Clearing Stem. The Wire (18) should remain in contact with the clog, using gentle pressure, for up to five (5) minutes. The length of time may depend on the amount of compacted material. It may also help to move the Clearing Stem backward approximately 4 in (10 cm) then forward 4 in (10 cm). Repeat the backward and forward movement several times. **IT IS IMPORTANT TO NOTE THAT THE CLEARING STEM NEEDS TO DO THE WORK. ANY SIGN OF WIRE KINKING DUE TO OPERATOR FORCE WILL DECREASE THE CLEARING EFFICACY.**
- 5.21) Continue in this manner until the Collar (17) reaches the nasogastric tube's external port (20) as illustrated in **Figure 9**. If this does not occur within five (5) minutes, refer to **Section 10** Troubleshooting Guide.
- 5.22) **NOTE:** The TubeClear™ Control Box (5) will automatically turn off after operating for ten (10) minutes. The Control Box may be re-started by pushing down the Start/Stop Button (8).
- 5.23) After the Collar (17) reaches the nasogastric tube's external port (20) as illustrated in **Figure 9** (see page 14), move the Clearing Stem (12) backward approximately 4 in (10 cm) then forward until the Collar reaches the nasogastric tube's external port again.

FIGURE 9: The Collar Limits Insertion of the Clearing Stem.

The Collar limits further insertion into the nasogastric tube.



- 5.24) With the Control Box (5) ON, slowly remove the Clearing Stem (12) and repeat Steps 5.15 - 5.23 **at least two (2) times**. This will help to clear any material that remains near the stomach end of the nasogastric tube. Additional backward and forward movement may be necessary to clear clogged material.
- 5.25) With the Control Box (5) ON, slowly remove the Clearing Stem (12) from the nasogastric tube.
- 5.26) Turn off the Control Box (5) by pressing down the Start/Stop Button (8). *(Switching the On/Off Power Switch (6) to the OFF position and unplugging the Power Cord (1) will also turn off TubeClear™.)*
- 5.27) **Do NOT detach the Clearing Stem (12) from the Control Box (5) until you reach Step 5.32.**
- 5.28) With the Magnet Adapter (14) attached to the Control Box (5), loosely coil the Clearing Stem (12) and place it back into the Packaging until Step 5.31 is completed.
- 5.29) Verify that the nasogastric tube is properly placed in the stomach using your Institution's protocol.
- 5.30) Verify that the Patient's nasogastric tube is clear using your Institution's Protocol.

- 5.31) If the nasogastric tube is still clogged, repeat Steps 5.13 - 5.30 with TubeClear™.
- 5.32) After verifying the nasogastric tube is clear, disconnect the Clearing Stem (12) from the Control Box (5) by gently lifting the Stem Lock (13) out of the Bracket Adapter (15) and then gently pulling upward on the Magnet Adapter (14) to separate it from the Diaphragm (11).
- 5.33) Replace the Plastic Cap (19) on the Magnet Adapter (14) of the Clearing Stem (12) prior to disposal.
- 5.34) Do **NOT** dispose of the Clearing Stem (12) with ordinary waste. Dispose of the Clearing Stem as regulated medical waste in accordance with applicable government regulations and your Institution's Protocol.
- 5.35) If any of the de-clogged contents from the nasogastric tube come into contact with the Patient or any surfaces, consider the de-clogged contents to be similar to vomitus. Clean the Patient and surfaces in accordance with your Institution's Protocol.

6.0 Control Box Cleaning Instructions



Turn off and unplug the Control Box (5) prior to cleaning.



Thoroughly clean the Control Box (5) after each use.

- 6.1) To clean the Control Box (5), use 1) a nonabrasive cloth dampened with isopropyl alcohol, or 2) disinfectant wipes. Wipe over exterior surfaces.
- 6.2) To clean the Diaphragm (11), use 1) a nonabrasive cloth dampened with isopropyl alcohol, or 2) disinfectant wipes. Carefully wipe over the surface.
- 6.3) Do **NOT** clean the Clearing Stem (12). The Clearing Stem is designed for **SINGLE USE**. It should not be reused under **ANY** condition. Dispose of the Clearing Stem in the Packaging as regulated medical waste in accordance with applicable government regulations and your Institution's Protocol.

7.0 Maintenance

Other than careful cleaning of the Control Box after each use, TubeClear™ does not require maintenance.

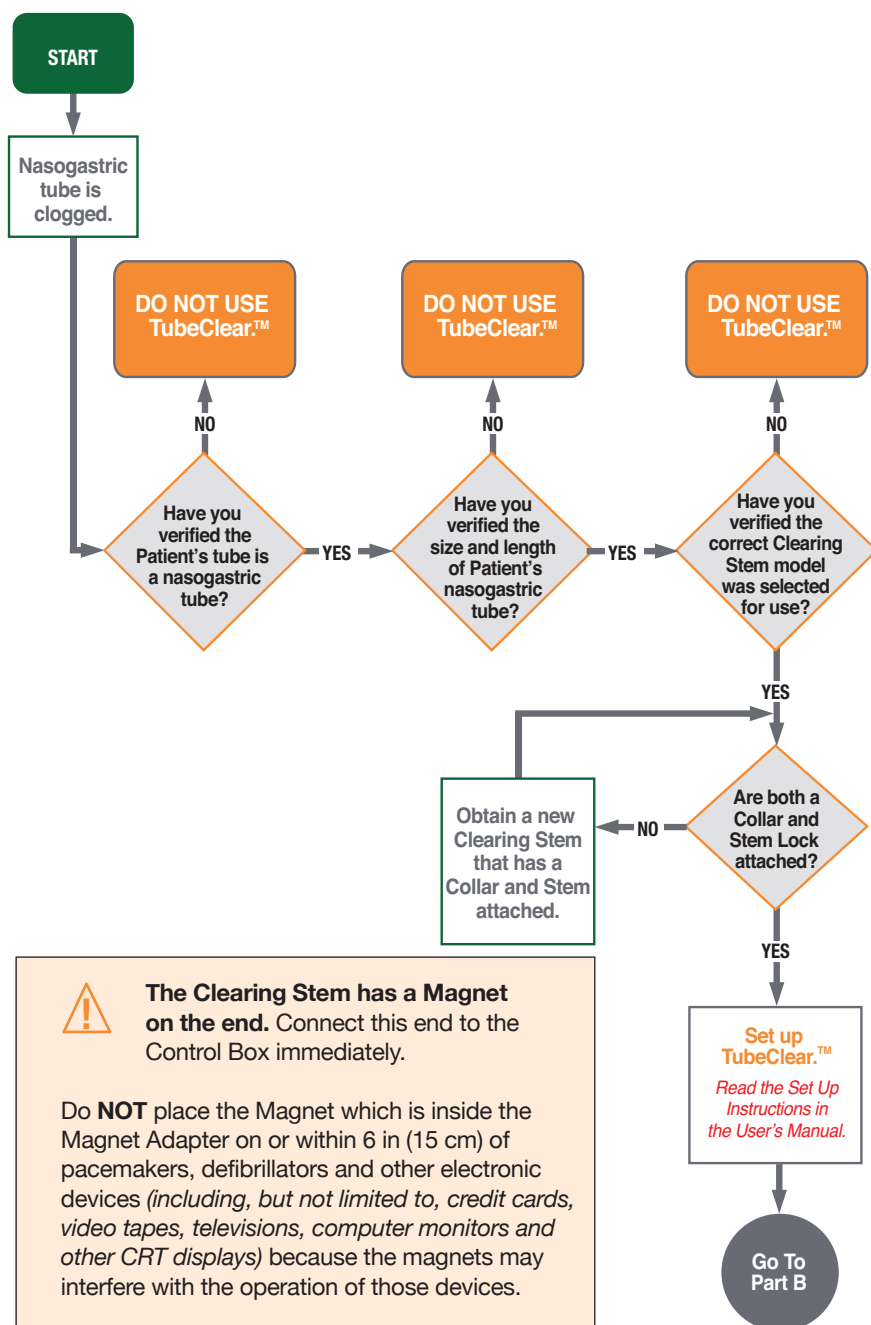
8.0 Storage

Store the Control Box (5) and any unused Clearing Stems in a clean, dry area. It is recommended that the Control Box and Clearing Stems be stored at temperatures between 32°F to 95°F (0°C to 35°C) and at a relative humidity less than 60%.

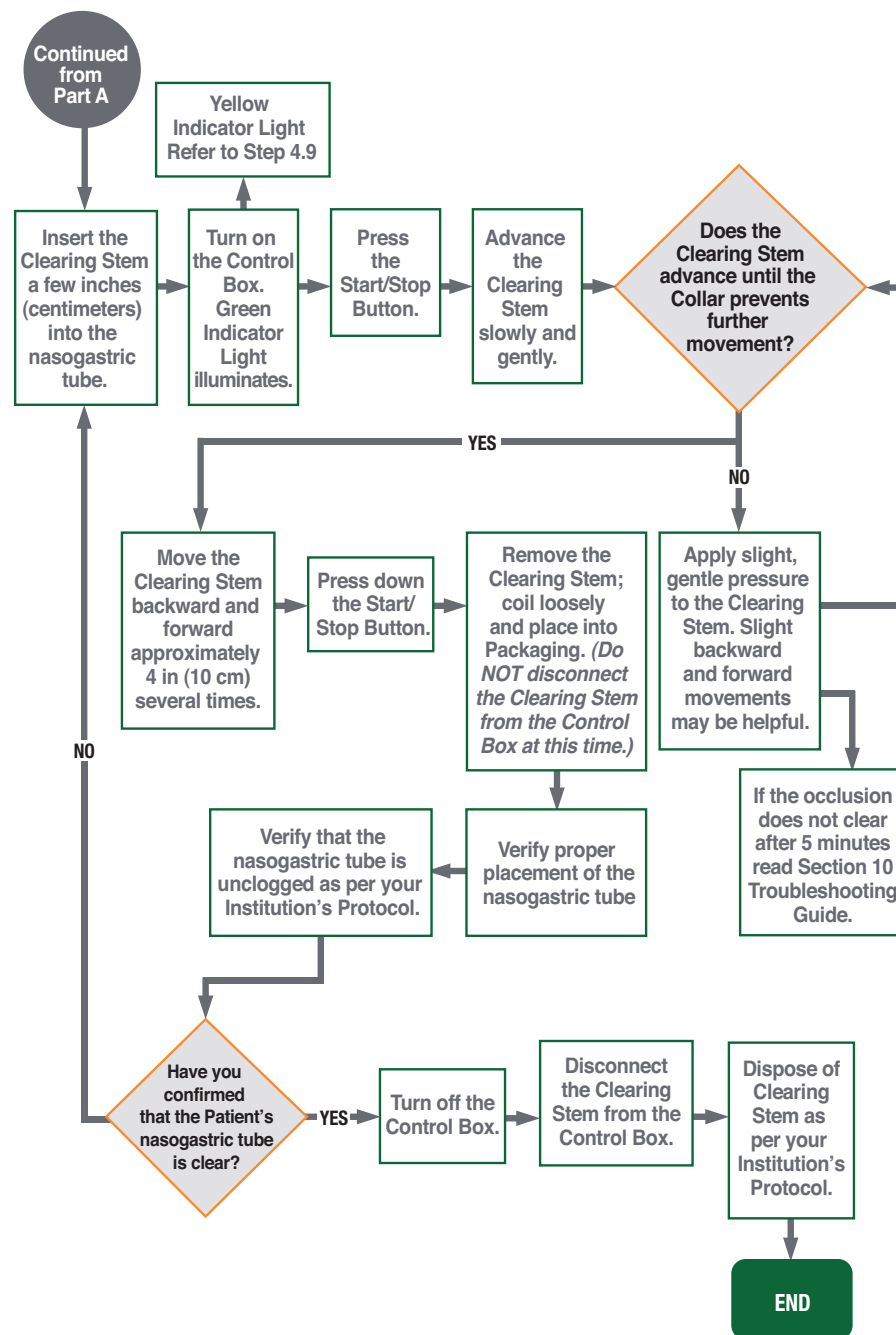
9.0 Return Policy

Actuated Medical, Inc. (AMI) takes pride in the quality of our products. If you are not satisfied with our products or if the TubeClear™ Control Box stops working within twelve (12) months from the initial date of shipment, contact our Customer Service Department at **814-355-0003 ext. 100** for a prompt replacement. You will be provided with a Return Authorization (RA) number and return shipping information. *All returns must be accompanied by a RA number and reason(s) for return.*

FLOW DIAGRAM PART A: Flow Diagram for Operation of TubeClear™



FLOW DIAGRAM PART B: Flow Diagram for Operation of TubeClear™



10.0 Troubleshooting Guide

Issue	Solution Options
If the Wire is not moving or is moving slowly.	+ The Clearing Stem may be bent or curled near the Control Box Bracket Adapter. If so, straighten the Clearing Stem. + The Magnet Adapter may not be well attached to the Control Box Diaphragm (see Figure 5). + The Stem Lock may not be firmly secured in the Control Box Bracket Adapter (see Figure 6). + The Clearing Stem may be too tightly wrapped around your hand (see Figure 7).
If the clog has not been cleared after 5 minutes of operation. IT IS IMPORTANT TO NOTE THAT THE CLEARING STEM NEEDS TO DO THE WORK. ANY SIGN OF WIRE KINKING DUE TO OPERATOR FORCE WILL DECREASE CLEARING EFFICACY.	Refer to the Doctor's Orders to verify that the use of water is permitted. If permitted, remove the Clearing Stem and add 20 - 30 ml of water; allow the water to set for approximately one minute. Then repeat the procedure from Section 5.0 Steps 5.13 - 5.30. If the use of water is not permitted, review additional troubleshooting tips. If the Clearing Stem keeps stopping at the same point within the nasogastric tube, there might be a clog formed from packed materials. Keep applying gentle pressure to the Clearing Stem. However, too much force will dampen out the Wire movement and decrease Clearing Stem efficacy. Apply gentle force allowing the Clearing Stem to break up the clog.
If the clog has not been cleared after 10 minutes of operation.	Remove the Clearing Stem from the nasogastric tube and verify the Wire is moving backward and forward. If the Wire moves freely while the Clearing Stem is outside of the nasogastric tube, repeat the procedure from Section 5.0, Steps 5.13 - 5.30. The clog may be particularly difficult to clear or there may be multiple clogs throughout the nasogastric tube. If movement of the Wire is blocked due to clog material being in the Sheath, replace the Clearing Stem with a new Stem and repeat from Section 5.0, Steps 5.14 - 5.37. The Clearing Stem Sheath may have become packed with clog materials. If the Clearing Stem appears to be damaged, replace with a new Clearing Stem and try again. Use less force and allow the Clearing Stem to do the work.
If the clog has not been cleared after 20 minutes of operation.	The tube could have a kink. The clog may be further down the nasogastric tube than the Clearing Stem can reach. Alternate procedures should be implemented; follow your Institution's Protocol for treating a clogged nasogastric tubes.

11.0 Technical Data

11.1) Environmental Conditions that Affect Use

Operating conditions: From 32°F to 95°F (0°C to 35°C).
Relative humidity from 30% to 75%.

 Transport and storage conditions: From -4°F to 140°F (-20°C to 60°C). Relative humidity from 10% to 90%.

11.2) Classification - TubeClear™ is:

- + classified as IEC Class II Equipment. 
- + classified as Type B applied part. 
- + an externally-powered device.
- + type IPX4.
- + non-sterile.
- + **NOT** suitable for use in the presence of flammable anesthetics.
- + suitable for continuous operation.

11.3) Accessories

- + Power Cord – Hospital Grade, Unshielded, IEC320 Connector, RoHS Compliant.
- + Power Supply (Transformer) – Input: 100 - 240 V, 50/60 Hz, Output: 24VDC, up to 2.71A, 3-pin IEC 320 Inlet, RoHS Compliant.

 Use of Power Supplies and Power Cords other than those specified in **Section 3.0** may result in improper functioning of TubeClear™ and increased emissions or decreased immunity of TubeClear™.

11.4) Electromagnetic Emissions / Immunity

Guidance regarding electromagnetic emissions and electromagnetic immunity is presented in **Table 3**, **Table 4**, **Table 5** and **Table 6**.

**TABLE 3: Guidance & Manufacturer's Declaration –
Electromagnetic Emissions**

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	TubeClear™ Control Box Model 101 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliant	
TubeClear™ Control Box Model 101 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.		

TubeClear™ Control Box Model 101 is intended for use in the electromagnetic environment specified above.

The Operator of TubeClear™ Control Box Model 101 should assure that it is used in such an environment.

**TABLE 4: Guidance & Manufacturer's Declaration –
Electromagnetic Immunity**

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) EN/IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN/IEC 61000-4-4	± 2kV Mains ± 1kV I/Os	± 2kV Mains ± 1kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN/IEC 61000-4-5	± 1kV differential ± 2kV common	± 1kV differential ± 2kV common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout EN/IEC 61000-4-11	>95% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles >95% dip for 5 Seconds	>95% dip for 0.5 cycle 60% dip for 5 cycles 30% dip for 25 cycles >95% dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the Operator of TubeClear™ Control Box Model 101 requires continued operation during power mains interruptions, it is recommended that TubeClear™ Control Box Model 101 be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) Magnetic Field EN/IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

TubeClear™ Control Box Model 101 is intended for use in the electromagnetic environment specified above.

The Operator of TubeClear™ Control Box Model 101 should assure that it is used in such an environment.

TABLE 5: Guidance & Manufacturer's Declaration – Emissions Equipment and Systems that are NOT Life-Supporting

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment - Guidance
Conducted EN/IEC 61000-4-6	3 Vms 150 kHz - 80 MHz	3 Vms	Portable and mobile communications equipment should be separated from TubeClear™ Control Box Model 101 by no less than the distances calculated / listed below: $D = (3.5/V1)(\text{Sqrt } P)$
Radiated RF EN/IEC 61000-4-3	3 V/m 80 MHz - 2.5 GHz	3 V/m	$D = (3.5/E1)(\text{Sqrt } P)$ 80 - 800 MHz $D = (7/E1)(\text{Sqrt } P)$ 800 MHz - 2.5 GHz Where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.

TubeClear™ Control Box Model 101 is intended for use in the electromagnetic environment specified above.

The Operator of TubeClear™ Control Box Model 101 should assure that it is used in such an environment.

TABLE 6: Recommended Separation Distances for TubeClear™ Control Box Model 101

Max Output Power (Watts)	Separation (m) 150 kHz - 80 MHz $D=(3.5/V1)(\text{Sqrt } P)$	Separation (m) 80 MHz - 800 MHz $D=(3.5/E1)(\text{Sqrt } P)$	Separation (m) 800 MHz - 2.5 GHz $D=(7/E1)(\text{Sqrt } P)$
0.01	0.1166	0.1166	0.2333
0.1	0.3689	0.3689	0.7383
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.6666	11.6666	23.3333

TubeClear™ Control Box Model 101 is intended for use in the electromagnetic environment in which radiated disturbances are controlled.

The Operator of TubeClear™ Control Box Model 101 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and TubeClear™ Control Box Model 101 as recommended above, according to the maximum output power of the communications equipment.